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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,919	03/26/2004	Thomas Wisniewski	57953/1211 (2003-11-WIS02	9386

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EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,919	WISNIEWSKI ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *26 and 212* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on July 10, 2006 is acknowledged. The traversal is on the ground(s) that 'the claims of the present application are closely related and, therefore, require common areas of search and consideration". This has been found to be persuasive in part and claims 12-20 have been rejoined with Group I. However, Group IV encompasses an invention that is independent and distinct for reasons of record in Paper mailed on January 26, 2006. An application may properly be required to be restricted to one of two or more claimed inventions if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05 (i)). Furthermore, MPEP § 803 provides that the separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions would impose a serious burden upon the Examiner, such separate classification presented in Office action mailed on January 26, 2006.

The requirement is still deemed proper and is therefore made FINAL.

Claims 21-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 10, 2006.

Claims 1-20 are under examination in the instant office action.

Drawings

2. The figures of the instant application are presented on separate pages or in separate panels. 37 C.F.R. § 1.84(u) (1) states that in cases when figures present partial views of a drawing, which are intended to form one complete view, whether contained on one or several sheets, the figures must be identified by the same number followed by a capital letter. For example, the two pages of Figure 1 in the instant specification should be renumbered "Figure 1A" – "Figure 1B" rather than "Figure 1 (A), (B)". Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(u) (1), the specification should be amended to change the Brief Description of the Drawings and the rest of the specification to refer to each Figure accordingly. If, for example, Figure 1 is divided into Figures 1A-1B, then the Brief Description and all the references to this figure in the specification must refer to this Figure in the same manner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-11 are directed to methods of preventing or treating Alzheimer's Disease (AD) by administration of an agent that inhibits interaction between amyloid-β and proteins which chaperone amyloid-β. Claims 12-20 encompass methods of inhibiting accumulation of amyloid-β deposits by administration of an agent that inhibits interaction between amyloid-β and proteins which chaperone amyloid-β. However, the instant specification fails to provide enough guidance for one skilled in the art on how to practice the instant methods, thereby requiring undue experimentation to discover how to use Applicant's invention, as currently claimed.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

With respect to claims breadth, Applicant is advised that claims 1-20 are single means claims in that they recite "an agent which inhibits interaction", which is exemplified in the instant specification as "a protein or a peptidomimetic" or "a non-proteinaceous" agent (see [0023-0024] of the instant specification). MPEP 2164.08(a) defines a single means claim as a claim which covered every conceivable means for achieving the stated purpose when the specification disclosed at most only those means known to the inventor. This type of claim was held to be nonenabling for the scope of the claim in *In re Hyatt* , 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983) because the specification disclosed at most only those means known to the inventor. When claims depend on a recited property (i.e. ability to inhibit interaction), a fact

situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. This appears to be the instant case and the claims are not commensurate in scope with the specification. Applicant should note that the claims encompass such things as administration of lethal drugs to achieve "inhibition of interaction between amyloid-β" and other proteins due to the definition of "an agent" in the specification and further in view of the lack of point of reference for the degree of inhibition, see reasoning in section 8 below.

The nature of the invention is the demonstration that amyloid-β peptide 12-28P (peptide of SEQ ID NO: 4, Aβ12-28P) causes reduction in amyloid plaque formation, as shown within cell-free system (Fig. 1, 3, and Examples 3, p.18 and 5, pp.19-20) as well as *in vivo* in experiments using transgenic mice (Fig. 6 and 7, Examples 8-10 and 17, pp.24-26 and 31-32). Also, administration of Aβ12-28P increased cell viability in culture (Fig. 2, Example 4, p.19 and Example 14, p.29). The beneficial effect of the fragment of the amyloid β peptide 12-28, wherein at position 18 Val is substituted for Pro, appears to be novel. However, the claims, as written, encompass:

(1) administration of any agent that inhibits interaction between amyloid β in general and proteins which chaperone amyloid β;

(2) treatment of Alzheimer's disease (AD) by administration of an agent;

(3) prevention of AD by administration of an agent;

and the instant specification does not provide any guidance as how to practice the full scope of the methods as currently claimed.

While the skill level in the art is high, the level of predictability is low. With respect to claims breadth, as fully explained earlier in the instant office action, the instant specification is not enabling for administration of any agent that affects interaction between amyloid β and other proteins because the specification does not provide any information regarding nature of interaction, degree of inhibition or disclosure of the effective conditions for such administration. While it is not necessary that Applicant understands or discloses the mechanism by which the invention functions, in this case, in the absence of such an understanding, no extrapolation can be made of the results obtained with using very specific molecular embodiment(s) of amyloid β peptides to other agents, "proteins or peptidomimetics", in view of the absence of evidential support or sound scientific reasoning to support such extrapolation.

Further, with respect to treatment of AD, the art clearly recognizes that dementia of Alzheimer's type is not limited to amyloid pathology. For example, in a review article by Sisodia et al. (FASEB Journal, 1995, Vol. 9, No. 5, pp.366-70), it is stated that morphologically AD is characterized by two major structural abnormalities of the brain: extracellular deposits of Aβ and neurofibrillary tangles composed of hyperphosphorylated tau (p.366). The instant specification discloses that administration of Aβ12-28P could lead to beneficial reduction of amyloid plaque formation. However, there appears to be no factual evidence or logical explanation presented at the time of filing to support a conclusion that administration of Aβ12-28P would lead to the treatment of AD.

Finally, it is well recognized in the art that as etiology of AD is unknown, "there is no effective treatment currently available to reverse, slow down or prevent" the course of AD (Vickers, Drug Aging, 2002, 19 (7), pp.487-94). The instant specification presents no guidance

how to practice the claimed methods with respect to prevention of AD, as currently claimed. There are no working examples, actual or prophetic, and no reference to prior art as how a similar method, which lead to prevention of amyloid plaque accumulation, was practiced. Therefore, it would require undue experimentation on part of a skilled practitioner to discover how to practice Applicant's invention commensurate in scope with the instant claims.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one cannot follow the guidance presented therein and practice the claimed methods without first making a substantial inventive contribution.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1-3 and 12-14 are vague and indefinite for recitation "amyloid-β". It is not clear and cannot be determined from the claims or the instant specification if the term encompasses amyloid-β peptide(s), or amyloid-β deposits, fibrils, aggregates etc. Clarification is required.

8. The term "inhibit(s)" in claims 1 and 12 is a relative term which renders the claims indefinite. The instant specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant is advised that until point of reference is provided as to determine the degree of inhibition, the metes and bounds of the claims cannot be definitively interpreted.

9. Claims 1 and 12 are further vague and indefinite because it is not clear and cannot be determined from the claims or the instant specification as filed as to how many proteins are involved in the process that intended to be inhibited by administration of an agent. Clarification is required.

10. Claims 1 and 12 are vague and ambiguous for recitation "under conditions effective to". It is not obvious and cannot be determined from the claims if the "conditions" are limited to doses and regimes of administration of an agent or encompass any other specific limitations.

11. Regarding claims 6 and 17, the phrase "like that of" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "like that of"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

12. Furthermore, claims 6 and 17 are indecipherable for recitation "the agent has a three dimensional structure". It appears that all molecules/agents have three-dimensional structure, unless specifically limited to 2D embodiments. Applicant is advised to rewrite the claims to better express the claimed subject matter.

13. Claims 4-5, 7-11, 15-16 and 18-20 are indefinite for being dependent from indefinite claims.

Conclusion

14. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
Art Unit 1649

September 6, 2006